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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO | | |
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| 10/003,030 | 10/29/2001 | Joseph H. Jackson III | LJL 367 | 1206 | | |
| | 590 08/20/2003 | DE A SERCUOPE | | | | |
| MCDONNELL BOEHNEN HULBERT & BERGHOFF 300 SOUTH WACKER DRIVE SUITE 3200 | | | EXAMI | EXAMINER | | |
| | | | SUNG, CHRISTINE | | | |
| CHICAGO, IL 60606 | | | ART UNIT | PAPER NUMBER | | |
| | | • | 2878 | | | |

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| • | - | Application No. | Applicant(s) | | | | |
|---|--|------------------------------------|---|------|--|--|--|
| Office Action Comments | | 10/003,030 | JACKSON ET AL. | MU | | | |
| | Office Action Summary | Examiner | Art Unit | | | | |
| | | Christine Sung | 2878 | | | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with the c | orrespondence add | ress | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | | |
| 1)🛛 | Responsive to communication(s) filed on 29 C | October 2001 . | | | | | |
| 2a) <u></u> □ | This action is FINAL . 2b)⊠ Thi | is action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| • | on of Claims | | | | | | |
| - | Claim(s) <u>1-68</u> is/are pending in the application | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| · · | Claim(s) is/are allowed. | | | | | | |
| • | 6)⊠ Claim(s) <u>1,2,4-8,10-13,17-30,32-39 and 41-66</u> is/are rejected. | | | | | | |
| 7)⊠ | 7)⊠ Claim(s) <u>3,9, 14-16,31,40,67-68</u> is/are objected to. | | | | | | |
| • | Claim(s) are subject to restriction and/o ion Papers | r election requirement. | | | | | |
| 9) 🗌 | The specification is objected to by the Examine | r. | | | | | |
| 10)⊠ The drawing(s) filed on <u>10/29/2001</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority (| ınder 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachmen | • | | | | | | |
| 2) Notice | ce of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 5) Notice of Informal I | y (PTO-413) Paper No(s Patent Application (PTO | | | | |

DETAILED ACTION

Claim Objections

1. Claim 31 is objected to because of the following informalities: The claim discloses discarding the light of the third wavelength, but a third wavelength is not described in claim 29. The claim lacks antecedent basis. It is unclear as to whether the claim dependency is incorrect or if the wavelength is actually the second wavelength. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1-2, 13, 23-24, 28-29, 33, 39 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Vo Dinh (US Patent 5938,617).

Regarding claims 1 and 28-29, Vo Dinh discloses in figure 2, a light source (element 22) with certain first wavelength (Column 5, lines 14-15); a wavelength converter (element 26) configured to receive the light of the first wavelength to convert that light into light of a second wavelength, where the second wavelength is different than the first wavelength (Column 5, lines 18-19); a system for directing the light of the second wavelength to an examination area (see figure 2, elements 28, 30, 32, and 34); a detector (element 38) configured to receive luminescence light from a sample positioned in the examination area (Column 5, lines 31-32).

Regarding claim 2, Vo Dinh further discloses that the light source can be a pulsed laser (element 22, column 5, lines 16-17).

Regarding claim 13, Vo Dinh further discloses a wavelength selector or laser dye unit for selecting the second wavelength (see figure 3, and column 5, line 54-column 6 line 2).

Regarding claims 23-24, Vo-Dinh discloses that the detector is an imaging detector that could be a CCD (column 7, lines 20-23).

Regarding claims 33 and 41-43 it is an inherent property of luminescence that illumination of a phosphor and detection of the luminescence is time dependent, meaning that the illumination of the sample results in an emission of light that decays over a period of time.

Therefore the light is used to determine a time dependent property of the sample. Further, it is an inherent property of luminescence that there is an excited state lifetime for the phosphor in the sample.

Regarding claim 39, it is an inherent property of luminescence that illumination photochemically activates the sample component and Vo-Dinh discloses a luminescence detection system.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 2878

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 4, 6-8, 10, 12, 17 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo-Dinh (US Patent 5,938,617).

Regarding claim 4, Vo-Dinh does not specifically disclose discarding data corresponding to a first set of laser pulses. However it is well known in the art that a warming up mode may be used to warm up the laser by pulsing it and taking measurements so that during operation the laser provides a uniform and consistent pulse throughout measurement. It is customary to include a trial run where the apparatus is given time to properly warm up and calibrate itself. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included a trial run where the first set of data is collected and discarded.

Regarding claim 6, although Vo-Dinh does not specifically disclose the use of a YAG laser, this type of laser is well known in the art. Therefore it would have been obvious to one having ordinary skill in the art at the time then invention was made to have used this specific type of laser as it is only a matter of design choice.

Regarding claim 7, Vo-Dinh discloses that the wavelength converter may include an optical parametric oscillator.

Regarding claims 8 and 30, Vo-Dinh discloses the conversion of the light from a first to a second wavelength, but does not disclose a conversion from the second to a third wavelength. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have had another wavelength converter to convert the second wavelength of radiation to

Art Unit: 2878

a third wavelength, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 549 F2d. 833, 193 USPQ8 (CA7, 1977).

Regarding claims 10 and 12, Vo-Dinh does not specify discarding the light of a third wavelength. However it is well known in the art to discard wavelengths not used or necessary for detection. Further the discarded wavelengths are typically directed away from the detector or can be absorbed in order to remove the undesired wavelengths. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have discarded undesirable wavelengths in order to reduce the erroneous readings that could result from exposure from undesirable radiation.

Regarding claim 17, Vo-Dinh does not specify the use of a beam splitter to direct the light to the detector, however it is well known that beamsplitters may be used to direct light. Vo-Dinh uses a lens, but it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a beamsplitter in place of the lens to direct the light to the detector, since it is recognized as an analogous optical element, for directing light to a specified location.

7. Claims 18-22, 26-27, 32, 34-38 and 44-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo-Dinh (US Patent 5,938,617) in view of Hielscher et al. (US Patent 6,011,626).

Regarding claims 18, 22, 34, 35, 44 and 61-62, Vo-Dinh discloses a light detection device comprising:

Art Unit: 2878

a light source (Figure 2, element 22) for exciting luminescence with certain first wavelength (Column 5, lines 14-15);

a wavelength converter (element 26) configured to receive the light of the first wavelength to convert that light into light of a second wavelength, where the second wavelength is different than the first wavelength (Column 5, lines 18-19);

an optical relay structure configured to project light onto an examination area (see figure 2, elements 28, 30, 32, and 34);

and a detector (element 38) configured to receive luminescence light from a sample positioned in the examination area (Column 5, lines 31-32). Vo-Dinh does not disclose an optical pattern generator, and further does not specify that the optical relay structure be configured to project light in a pattern form and that the pattern would conform to the sample. Hielscher et al. discloses a detection system whereby a polarizer (element 14) or optical pattern generator is configured to convert light into light having preselected intensity pattern. Further, Hielscher et al. discloses an optical relay system for projecting the light onto an examination area to form a projected pattern that substantially conforms to the sample (see Figure 2a and 2b). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the polarizer and optical relay system as disclosed by Hielscher et al. with the invention as disclosed by Vo-Dinh because including a polarizer with a patterned grid enhances the accuracy and uniformity of intensity over the sample, which allows for greater accuracy in luminescence measurements and reduces erroneous measurements.

Regarding claim 19, a microplate with welled sites is a well known type of sample holder in the art, and using it with the invention as disclosed by Vo-Dinh in view of Hielscher et al.

Art Unit: 2878

would only involve a matter of design choice, as selecting the type of sample holder only

involves routine skill in the art.

Regarding claims 20-21 and 59-60 Vo-Dinh discloses a first path that is defined by an optical fiber (element 88) and a second path that is defined by another optical fiber (element 94). Although he does not specify the orientation of the paths with respect to each other, optical fibers can be constructed to be oriented in whatever configuration necessary. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have oriented the paths either anti parallel or parallel to each other, since it only involves routine skill in the art to position the fibers into desired positions.

Regarding claims 26 and 27, Hielscher discloses a suspended sample that includes a fluid (see abstract). The delivery of the fluid into the suspension is obviously done before the commencement of the measurement. Fluid dispensers are well known in the art, and although Hielscher does not disclose such as dispenser, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included such a dispenser to regulate the amount of fluid necessary for each sample.

Regarding claims 32 and 63, Vo-Dinh discloses that the sample includes a luminescent material that is responsive to incident radiation. Further since the sample includes objects such as organs or other cellular materials, the emission radiation from the sample is indicative of properties relating to the organ, i.e. tissue density. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have correlated the emitted light to a property of the sample, i.e. tissue density (see abstract).

Art Unit: 2878

Regarding claim 36, Vo-Dinh discloses directing the second wavelength light onto the sample (see figure 2); measuring the light from the sample (see figure 2, element 38); correlating the light from the sample with a characteristic of the sample (see abstract).

Regarding claims 37 and 38, Vo-Dinh discloses measuring the sample or organ in one reading, thus the entire sample is measured all at once. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have had a divided sample where the sample is measured all at once as it would only be a matter of design choice to use a divided sample holder.

Regarding claim 45, Vo Dinh further discloses that the light source can be a pulsed laser (element 22, column 5, lines 16-17).

Regarding claims 46-48, Hielscher et al. discloses an optical pattern generator that is a polarizer, which is a diffractive element. He does not disclose specifically using a lens, mirror array or fold mirror, however it is well known in the art that these are equivalent optical pattern generators and can be interchanged to direct radiation in a pattern.

Regarding claim 49-52 and 55, Hielcher discloses an optical pattern generator or polarizer, with a certain intensity pattern, but does not limit what type of pattern must be used with his invention. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have use a periodic pattern, a particularly directed pattern, a spotted array pattern, or a uniform intensity pattern as all of these are within the scope of polarizers disclosed by Hielscher.

Regarding claims 53-54 and 56, the type, number or divisions of the sample holder are within the scope of accepted or analogous sample holders that are well known in the art.

Art Unit: 2878

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a biochip, a selected sample division, a microplate,

Regarding claims 57-58, Vo-Dinh discloses that the detector is an imaging detector that could be a CCD (column 7, lines 20-23) that receives luminescence from the sample (see figure 2).

Regarding claims 64-66 it is an inherent property of luminescence that illumination of a phosphor and detection of the luminescence is time dependent, meaning that the illumination of the sample results in an emission of light that decays over a period of time. Therefore the light is used to determine a time dependent property of the sample. Further, it is an inherent property of luminescence that there is an excited state lifetime for the phosphor in the sample.

8. Claims 11 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo Dinh (US Patent 5,938,617) in view of Stone et al. (US Patent 5,477,332).

Regarding claim 11, Vo Dinh does not specify the use of a spectral filter to discard unwanted radiation. It is well known in the art and further, is demonstrated by Stone, that spectral filters are used to reduce and eliminate unwanted radiation. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included a spectral filter to remove unwanted radiation to increase the accuracy of the desired measurements and decrease the possibility of erroneous measurements.

Regarding claim 25, the limitations set forth in claim 1 have been disclosed in the abovementioned paragraphs. Vo-Dinh does not specify the use of a spectral filter to preferentially block light of the first wavelength and substantially transmit light of the second wavelength. However it is well known in the art to use spectral filters to allow desired radiation

Art Unit: 2878

spectra to pass to the sample of interest. For example, Stone et al. discloses an imaging system including a spectral filter for restricting radiation to a desired radiation spectrum (column 5, lines 55-58). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included a spectral filter to prevent radiation of an undesired spectrum to reach the sample or detection unit.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vo Dinh (US Patent 5,938,617) in view of Spangenberg (US Patent 5,973,842).

Vo Dinh discloses the limitations set forth in claim 1, but he does not disclose the use of a reference beam monitor. However, it is well known in the art to have a reference beam to monitor any fluctuations, which could denote errors in the laser or light source being used. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included a reference beam monitor, like the one disclosed in Spangenberg (Column 26, lines 56-59) in order to ensure that the radiation coming from the source is consistent between measurements or during readings.

Allowable Subject Matter

10. Claims 3, 9, 14-16, 40, 67-68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 3, none of the prior art of record discloses that the detector triggers the pulsed laser as it is used with the elements in claim 1. However, many prior art references disclose that the pulsed laser triggers the detector.

Art Unit: 2878

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Regarding claim 9, none of the prior art of record discloses the specifics of the relationship between the first, second and third wavelengths, namely that the sum of the energy of the second and wavelengths must equal the energy of the first.

Regarding claims 14-16, none of the prior art of record discloses the specifics of changing the wavelength selector by changing the relative angle between the light and the wavelength converter. Although it is well known in the art to select specific wavelengths using laser dyes or other tuners, none of the prior art of record specifically discloses using changes in relative angles with the apparatus as disclosed in claim 1.

Regarding claim 40, none of the prior art of record discloses exposing the sample to an electrical potential to stimulate the sample.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Sung whose telephone number is 703-305-0382. The examiner can normally be reached on Monday- Friday 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 703-308-4852. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7722 for regular communications and 703-308-0956 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

Page 12

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August 8, 2003

DAVID PORTA

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